

(c) An informative statement of the nature and effect of any treatment or processing of the food or any ingredient thereof, if the changed allergenic property results from such treatment or processing.

§ 105.65 Infant foods.

(a) If a food (other than a dietary supplement of vitamins and/or minerals alone) purports to be or is represented for special dietary use for infants, the label shall bear, if such food is fabricated from two or more ingredients, the common or usual name of each ingredient, including spices, flavoring, and coloring.

(b) If such food, or any ingredient thereof, consists in whole or in part of plant or animal matter and the name of such food or ingredient does not clearly reveal the specific plant or animal which is its source, such name shall be so qualified as to reveal clearly the specific plant or animal that is such source.

[42 FR 14328, Mar. 15, 1977, as amended at 47 FR 947, Jan. 8, 1982; 49 FR 10090, Mar. 19, 1984; 50 FR 1840, Jan. 14, 1985]

§ 105.66 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any food that purports to be or is represented for special dietary use because of usefulness in reducing or maintaining body weight shall bear:

(1) Nutrition labeling in conformity with § 101.9, or, where applicable, § 101.36 of this chapter, unless exempt under that section; and

(2) A conspicuous statement of the basis upon which the food claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any food subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary food may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the food under the applicable

law and regulations of this chapter. Any food that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener, e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A food purporting to be "low calorie" must comply with the criteria set forth for such foods in § 101.60(b)(2) and (b)(3) of this chapter.

(d) *"Reduced calorie" foods and other comparative calorie claims.* A food purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such food in § 101.60(b)(4) and (b)(5) of this chapter.

(e) *Label terms suggesting usefulness as low calorie or reduced calorie foods.* (1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, and in § 101.13(q)(2) of this chapter for soft drinks, a food may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false and misleading, and the food is labeled "low calorie" or "reduced calorie" or bears another comparative calorie claim in compliance with part 101 of this chapter and this section.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the food is offered solely for a dietary use other than regulating body weight, e.g., "for low-sodium diets."

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other food that is represented to be of special dietary use as a whole meal, pending the issuance of a

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regulation governing the use of such terms on foods.

(f) “*Sugar free*,” and “*no added sugar*.” Criteria for the use of the terms “sugar free” and “no added sugar” are provided for in §101.60(c) of this chapter.

[58 FR 2430, Jan. 6, 1993]

§ 105.67 Label statement relating to food for use in the diet of diabetics.

(a) A food that purports to be represented for special dietary use because of usefulness in the diet of diabetics shall bear nutrition labeling in compliance with §101.9 of this chapter, unless exempt under that section, and the statement “Diabetics: This product may be useful in your diet on the advice of a physician. This food is not a reduced calorie food.” If the food is useful in maintaining or reducing calorie intake or body weight and labeled in conformity with §105.66, the last sentence may be eliminated.

(b) A food shall not be represented to be useful in the diets of diabetics if such representation is false or misleading.

(c) The term “diabetic,” “for diabetics,” “diabetes,” or the like, shall not be included as part of the name of any food, or otherwise be included on the labeling more prominently than the statement required by paragraph (a) of this section.

(d) The term “dietetic,” “diet,” or the like, shall not be included in the labeling of a food solely because of its possible usefulness in the diet of diabetics.

(e) A food shall not purport to be or be represented for special dietary use because of usefulness in the diet of diabetics solely by virtue of its being a food useful in reducing or maintaining caloric intake or body weight.

[43 FR 43259, Sept. 22, 1978]

§ 105.69 Foods used to regulate sodium intake.

If a food purports to be or is represented for special dietary use by man by reason of its use as a means of regulating the intake of sodium or salt (sodium chloride), the label shall bear either nutrition labeling or a statement of the number of milligrams of sodium

in a specified serving (portion) of such food, in conformance with the applicable provisions of §101.9 of this chapter.

[49 FR 15534, Apr. 18, 1984]

Subpart C [Reserved]

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PART 106—INFANT FORMULA QUALITY CONTROL PROCEDURES

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AUTHORITY: Secs. 201, 412, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 350a, 371).

SOURCE: 47 FR 17025, Apr. 20, 1982, unless otherwise noted.

Subpart A—General Provisions

§ 106.1 Status and applicability of the quality control procedures regulation.

(a) The criteria set forth in §§106.20, 106.25, 106.30, 106.90, and 106.100 shall apply in determining whether an infant formula meets the safety, quality, and nutrient requirements of section 412 of the act and the requirements of regulations promulgated under section 412(a)(2) of the act.

(b) The failure to comply with any regulation set forth in §§106.20, 106.25, 106.30, 106.90, and 106.100 applicable to the manufacturing, processing, and packaging of an infant formula shall